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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,853	05/26/2006	Hyun-Jin Park	1012679-000117	8824
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EXAMINER				
SUTTON, DARRYL C				
ART UNIT		PAPER NUMBER		
1612				
NOTIFICATION DATE		DELIVERY MODE		
06/11/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary

Application No.

10/580,853

Applicant(s)

PARK ET AL.

Examiner

DARRYL C. SUTTON

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-14 is/are pending in the application.
- 4a) Of the above claim(s) 1, 3-6, 10-12 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-9 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to the amendment filed 03/12/2009. No new claims have been added.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haasmaa et al. (US 2003/0032254) in view of Ohwada et al. (J. Appl. Glycosci., 2003).

Haasmaa et al. teach a hydrophobic polymer dispersion containing starch with dispersion admixtures. The dispersion can be used for the production of cast films or to coat medicinal preparations (Abstract and [0005]). The emphasis on environmentally friendly attitude is opening new markets based on renewable resources. Starch and its derivatives constitute a particularly interesting starting material for the production of biodegradable polymer products [0007]. A starch component may be based on any native starch having an amylose content of 0 to 100% [0026]. The dispersion composition may contain advantageously about 1-50% of any known plasticizer which gives the composition its plastic form [0031]. The dispersion contains a dispersion

admixture which allows for the formation of a stable dispersion [0032]. For example, the preparation of a hydrophobic starch dispersion about 1.0 kg of starch ester, about 0.5 kg of plasticizer and about 0.1 kg of admixture may be dispersed in 10 kg of water [0038]. This corresponds to a composition comprised of about 8.6% starch, about 4.3% plasticizer, about 0.9% admixture and about 86% water.

Haasmaa et al. do not teach a composition comprised of waterchestnut starch or mungbean starch, plasticizer and water or the specific amounts of each component; or the amylose content of the starch component; or the specific plasticizers of claim 9.

Ohwada et al. teach that Naivikul and D'Appolonia reported the amylose content of mungbean starch at 19.5 to 28.8% (page 482, 1st column, "Results and Discussion").

Ohwada et al. do not teach a composition comprised of mungbean starch, plasticizer and water.

Haasmaa et al. do not teach the specific amounts of starch, plasticizer and water in the composition. However, it would have been obvious to vary the amounts of each in light of the teaching that about 1.0 kg of starch ester, about 0.5 kg of plasticizer and about 0.1 kg of admixture may be dispersed in 10 kg of water. The term "about" permits flexibility, particularly where there is nothing in the record to indicate the precise metes and bounds of the term. See, e.g., Amgen v. Chugai, 18 USPQ2d 1016 (Fed. Cir. 1991); see also MPEP 2173.05 [R-6] A. Accordingly, varying the amount of starch to 0.85 kg versus about 1 kg of the prior art which affects the biodegradability; varying the amount of plasticizer to 0.35 kg versus 0.5 kg which affects the softness; varying the

amount of admixture to 0.09 kg versus 0.1 kg which affects the stability, would result in a composition comprised of approximately 8% starch ether, 3% plasticizer, 1% admixture and 88% water. Since "about" is given flexibility, each of the varied amounts is considered to be "about" the amounts disclosed in Haasmaa et al.

At the time of the invention, it would have been obvious to use the mungbean starch of Ohwada et al. as the source of starch in the compositions of Haasmaa et al. since Haasmaa et al. teaches that any native starch with an amylose content from 0 to 100% can be used as the starch source.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haasmaa et al. and Ohwada et al. as applied to claims 7 and 8 above, and further in view of Scott et al. (US 6,635,275).

Haasmaa et al. and Ohwada et al. are discussed above.

Haasmaa et al. and Ohwada et al. do not teach the specific plasticizers of instant claim 9.

Scott et al. teach compositions from modified starches, such as starch ethers, for pharmaceutical use in products like films and for formulations like soft and hard capsules (Abstract, column 1, lines 3-9). The compositions are comprised of plasticizers, such as glycerol, polyethylene glycol, sorbitol, in amounts from 0-30% (column 1, line 66 – column 2, line 12).

Scott et al. does not teach a composition comprised of mungbean starch, plasticizer and water.

At the time of the invention, it would have been obvious to use one of the plasticizers of Scott et al. as the plasticizer in the compositions suggested by combining Haasmaa et al. and Ohwada et al. since Haasmaa et al. teach that the composition is comprised of any known plasticizer.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haasmaa et al. and Ohwada et al. as applied to claims 7 and 8 above, and further in view of Wittwer et al. (US4,738,724).

Haasmaa et al. and Ohwada et al. are discussed above.

Haasmaa et al. and Ohwada et al. do not teach a film for a hard capsule.

Wittwer et al. teach compositions and methods of preparing hard shell capsules for pharmaceutical use (Abstract, column 1, lines 33-41, column 15, lines 27-31). The starches, modifications of starches or derivatives used in the invention advantageously contain about 0-70% amylose (column 7, lines 46-50). Pharmaceutically acceptable plasticizers, such as polyethylene glycol, or low-molecular weight plasticizers, such as glycerol, sorbitol are used in amounts of about 0.5-40% by weight (column 8, lines 63-68-column 9, lines 1-2). The capsules are further comprised of water (claim 1). Film casting is a method that may be used for the production of the capsules of the present invention (column 22, lines 4-8), i.e. the compositions can be prepared into a film.

Wittwer et al. do not teach a composition comprised of mungbean starch or of waterchestnut starch; or the weight percentages of water used.

At the time of the invention, it would have been obvious modify the compositions suggested by combining Haasmaa et al. and Ohwada et al. to be a film for a hard capsule, since Haasmaa et al. teach that the composition can be used for the production of cast films and Wittwer et al. teach that cast films comprised of modified starches with amylose content from 0 to 70%, plasticizers and water can be used for the production of films for hard capsules.

All claims are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612